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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/583,089 | 06/15/2006 | Andreas Nandy | MERCK-3178 | 8804 |

23599 7590 11/05/2009

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| EXAMINER | |
|---|---|
| ROONEY, NORA MAUREEN | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/05/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/583,089 | NANDY ET AL. | |
| | Examiner | Art Unit | |
| | NORA M. ROONEY | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *1-9,14-17 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's response filed on 07/28/2009 is acknowledged.

2. Claims 1-17 and 21-23 are pending.

3. Claims 1-9 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, and claim 23 is withdrawn from consideration as being directed to a non-elected species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/19/2008. It is noted that Applicant elected the species of SEQ ID NO:2 with or without the signal peptide. Claim 23, which is directed to variant polypeptides with one or more cysteine residues replaced with any amino acid reads on many different polypeptides and is not encompassed by the elected species.

4. Claims 10-13 and 21-22 are currently under examination as they read on the polypeptide of SEQ ID NO 2 with or without the signal sequence and a pharmaceutical composition thereof.

5. Applicant's certified copy of the English language translation of German priority application 103 59 351.9 filed on 03/25/2009 is acknowledged.

6. The following rejections are necessitated by the amendment filed on 07/28/2009.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10, 12-13 and claims 21-22 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for : the polypeptide encoded by the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof, the specification does not provide reasonable enablement for : a polypeptide which is encoded by **a DNA sequence** set forth in SEQ ID NO 1, 3, 5, 7 or 9 of claim 10 and as applied to claims 12-13 and 21-22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons as set forth in the Office Action mailed on 11/28/2008.

Applicant's arguments filed on 07/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

It is the Examiner's position that the term "a DNA sequence" in claim 10 opens up the claims to read on subsequences. It is suggested that the claim be amended to recite "the DNA sequence of SEQ ID NO:1.."

The specification discloses the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof.

9. Claims 10, 12-13 and claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : the polypeptide encoded by the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the polypeptide encoded by the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide; and compositions thereof.

Applicant is not in possession of a polypeptide which is encoded by **a DNA sequence** set forth in SEQ ID NO 1, 3, 5, 7 or 9 of claim 10 and as applied to claims 12-13 and 21-22.

Applicant's arguments filed on 07/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

"Thus it is respectfully submitted that the foregoing amendments render moot the written description rejection."

It is the Examiner's position that the term "a DNA sequence" in claim 10 opens up the claims to read on subsequences. It is suggested that the claim be amended to recite "the DNA sequence of SEQ ID NO:1.."

Applicant has disclosed only the DNA sequence of Isoform Sec c 4.01 (SEQ ID NO 1) and the protein of SEQ ID NO:2 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Sec c 4.02 (SEQ ID NO 3) and the protein of SEQ ID NO:4 with or without the 22 amino acid signal peptide; the DNA sequence of Hor v 4 (SEQ ID NO 5) and protein of SEQ ID NO 6 with or without the 22 amino acid signal peptide; the DNA sequence of Isoform Tri a 4.01 (SEQ ID NO 7) and the protein of SEQ ID NO:8 with or without the 21 amino acid signal peptide; the DNA sequence of Iso-form Tri a 4.02 (SEQ ID NO 9) and protein of SEQ ID NO 10 with or without the 21 amino acid signal peptide and compositions thereof.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 10-11 stand rejected and claims 21-22 are rejected are rejected under 35 U.S.C. 102(b) as being anticipated by Gavrovic et al. (PTO-892 mailed on 11/28/2008; Reference V) as evidenced by the specification on page 4, lines 1 and 19-22 for the same reasons as set forth in the Office Action mailed on 11/28/2008.

Newly added claim 21 is included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same

product are precluded, even if that product is claimed as made by a new process.

Applicant's arguments filed on 07/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

> "The rejection is based on the references' disclosure of allergens from *Secale cereale.* The Office Action has not established that such polypeptides are structurally and/or functionally identical to the polypeptide(s) comprising the sequences set forth in SEQ ID NOs. 2, 4, 6, 8, or 10, as claimed herein. More specifically, the totality of the disclosure in Gavrovic says nothing about the identity of the polypeptides of the present invention which are currently claimed. Absent such, the reference cannot anticipate what is claimed herein.
>
> Moreover, allergen proteins obtained form natural sources are always mixtures of several compounds and allergens isolated therefrom do not normally contain pure protein. This is the advantage of recombinantly prepared proteins and the subject matter of the present invention. Thus, the polypeptides claimed herein are not inherent in the reference, as the references do not disclose the recited sequences and isolated/purified forms thereof. See, the subject matter of the new claims. As such, the PTO's contentions are without merit. "

It remains the Examiner's position that Gavrovic et al. teaches the same isolated Sec c 4 protein isolated from the same Secale cereale source (In particular, abstract). Since the reference teaches the same isolated allergen from the same source, the allergen must necessarily have the sequence of SEQ ID NO:2 or SEQ ID NO:4. The recitation of the amino acid sequence of SEQ ID NO 2 and 4 in claim 10 and the amino acid sequences beginning with amino acid 23 in claim 11 adds no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render

the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". Further, contrary to Applicant's assertion, the reference Sec c 4 protein was isolated on a gel and characterized as being 55-60 kDa with a pI of 9.2 to 9.7. Since the office does not have a laboratory to test the reference sequences, it is applicant's burden to show that the reference molecules differ not due to sequencing error but due to a polymorphism. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980. Therefore, the rejection stands.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 10 and 12-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gavrovic et al. (PTO-892 mailed on 11/28/2008; Reference V) in view of WO 2004/000881 (Reference 2 on the IDS filed on 06/15/2006) and the corresponding U.S. Patent Application Publication 2006/0177470 A1 (PTO-892; Reference A) for the same reasons as set forth in the Office Action mailed on 11/28/2008.

Applicant's arguments have been fully considered, but are not found persuasive.

Applicant argues that the obviousness rejection of claims 10 and 12-13 over Gavrovic et al. in view of the disclosure in US patent application publication 2006/0177470 cannot stand.

It remains the Examiner's position that Gavrovic et al. teaches the same isolated Sec c 4 protein isolated from the same Secale cereale source (In particular, abstract). Since the reference teaches the same isolated allergen from the same source, the allergen must necessarily have the sequence of SEQ ID NO:2 or SEQ ID NO:4. The recitation of the amino acid sequence of SEQ ID NO 2 and 4 in claim 10 and the amino acid sequences beginning with amino acid 23 in claim 11 adds no patentable weight. Determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". Further, contrary to Applicant's assertion, the reference Sec c 4 protein was isolated on a gel and characterized as being 55-60 kDa with a pI of 9.2 to 9.7. Since the office does not have a laboratory to test the reference sequences, it is applicant's burden to show that the reference molecules differ not due to sequencing error but due to a polymorphism. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980. Therefore, the rejection stands.

The claimed invention differs from the prior art in the recitation of "a medicament comprising at least one polypeptide according to claim 10 and a carrier" of claim 12; and "a pharmaceutical composition comprising at least one polypeptide according to Claim 10 and an active ingredient or an adjuvant" in claim 13.

U.S. Patent Application Publication 2006/0177470 teaches the use of Group IV grass pollen allergens and homologous allergens in other species for diagnosis and therapy of allergic diseases (In particular, paragraph [0047). The reference also teaches pharmaceutical compositions and medicaments comprising these allergens that further comprise other active ingredients and adjuvants (In particular, paragraphs [0072]-[0076]).

It would have been obvious to one of ordinary skill in the art to use the allergens taught by Gavrovic et al. in a pharmaceutical composition or medicament further comprising other active ingredients or adjuvants for diagnosis or therapy because WO 2004/000881 and the corresponding U.S. Patent Application Publication 2006/0177470 teach the use of Group IV grass pollen allergens and homologous allergens in other species for diagnosis and therapy of allergic diseases.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the

contrary.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 27, 2009

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Maher M. Haddad/

Primary Examiner,

Art Unit 1644